NATIONAL ASSOCIATION OF Manufacturers

National Association of Manufacturers Response
to Questions from Special 301 Subcommittee of the Trade Policy Staff Committee
(Docket USTR-2020-0041)

March 5, 2021

1. In what ways, if any, should USTR take the COVID-19 pandemic into account when drafting the 2021 Special 301 Report? Please explain your reasoning.

The COVID-19 pandemic has marked a health and economic crisis unlike anything that our country has faced. The NAM and manufacturers in the United States are committed to be a part of the solution to end this pandemic, save lives and safeguard workers. Manufacturers are on the front lines, making safe and effective vaccines and treatments and other necessary provisions to help us fight the pandemic. The industry is committed to leveraging the full force of the "arsenal of democracy" and to promoting science-based actions to get us to the light at the end of this dark tunnel.

This pandemic has demonstrated the critical role of innovation, intellectual property and research and development in times of crisis. Protecting innovation and IP will be critical to our economic recovery—for creating well-paying jobs for Americans and their families and for driving entrepreneurship and small business creation. Such protections provide powerful incentives to create new products and for solutions not just to COVID-19, but also to other pressing global challenges, from climate change to transportation to infrastructure. Innovative new manufacturing processes spurred by the pandemic can also help lay the groundwork for a more competitive manufacturing base and more resilient supply chains.

As USTR is drafting this year's 2021 Special 301 report, it must recommit to strong American leadership to address global barriers to American innovation. It should champion strong global rules for IP protection, while engaging constructively with industry and with global partners to advance the COVID-19 response in ways that do not undermine our ability to respond to the next global crisis.

2. Your submission states that Saudi Arabia suffers from high levels of domestic counterfeiting.

a. Please elaborate on this statement, explain what "high levels" is in relation to, and provide recent studies, reports, or other data to support this statement.

b. What types of counterfeit goods is your submission referring to, and in what region are the goods being manufactured or sold?

NAM members report that various types of counterfeit products remain readily available across Saudi Arabia—ranging from auto parts to printer cartridges, from pharmaceuticals to mobile phone accessories to apparel. Within the country, counterfeit

goods are available in both wholesale and retail markets across the country, with hotspots in the cities of Riyadh, Jeddah and Dammam.

More broadly, both NAM members and broader studies report that most of these counterfeit goods are not produced in Saudi Arabia, but are imported from China or neighbouring UAE, and are either sold in country or re-exported to other global markets. Saudi Arabia's relationship with counterfeits is reflected in a range of public reporting and studies, including both global studies and local information sources.[1]

3. On Indonesia, your submission states that Presidential Regulation 77/2020, which "detailed the government's right to issue a compulsory license broadly for patents related to national defense, security or the vague circumstance of 'very urgent need in the public interest,'" raises "significant concerns for manufacturers in a wide range of sectors." Please elaborate on your concerns regarding Presidential Regulation 77/2020.

Indonesia has taken important steps in recent months to improve critical aspects of its IP system. In 2020, Indonesia's House of Representatives passed the Omnibus Bill on Job Creation, which deleted problematic provisions from its Patent Law requiring local manufacturing. These issues followed efforts over the past few years to revise existing compulsory licensing provisions to align with global norms, practices and processes, as well as ongoing steps to consider broader amendments to the Patent Law.

President Joko Widodo's July 2020 Presidential Regulation 77/2020, unfortunately, sent contrasting signals that undermine the global confidence in Indonesia's work to improve its IP system. The regulation was released with little notice or stakeholder consultation. It provides broad authority for the issuance of compulsory licenses with vague criteria such as a "very urgent need in the public interest." Troublingly, the regulation provides no detail as to how these criteria will be interpreted, what processes will be followed or how the government will ensure that all stakeholders have opportunities to engage and consult during the decision-making process. The regulation thus sends contradictory and confusing signals to innovative manufacturers about Indonesia's commitment to improving its IP and investment environment for manufacturers in the United States.

4. Your submission states that Australia "maintains a unique policy enabling the Department of Health to seek damages from patent holders that litigate granted patent claims and are granted preliminary injunctive relief but ultimately are unsuccessful in their litigation" and that this policy "has created a significant hurdle for companies seeking to enforce or defend their legitimate patent rights." In October 2020, the Australian Government announced planned reforms to the notification procedures for prescription medicines that are under evaluation.

[1] See, for example, "Saudi Customs destroy over 2 million counterfeit goods," Arab News, Nov. 30, 2020; Hanin Al Fayaz, "Social Media and the Fight against Counterfeiting in Saudi Arabia," Al-Tamimi Law Update, March 2018; World Customs Organization, "Illicit Trade Report: 2019," issues on July 30, 2020; and Organization for Economic Cooperation and Development and European Union Intellectual Property Office, "Mapping the Real Routes of Trade in Fake Goods," July 2017.

According to Australia, these reforms are intended to enhance transparency and to reduce the need for protracted and costly litigation.

a. Would these reforms address the concerns identified in your submission?

b. Please elaborate on your claim that this policy is "inconsistent with Australia's WTO commitments" under the TRIPS Agreement.

Australia's efforts to increase transparency in its notification processes for market approval of manufactured products such as prescription medicines are welcome. These reforms, however, do not address manufacturers' concerns with Australia's underlying policy that allows the Department of Health to seek damages from patent holders that litigate granted patent claims and are granted preliminary injunctive relief but ultimately are unsuccessful in their litigation. These reforms do not alter that underlying policy, and the Australian government has continued to signal that they intend to continue implementation of that policy.

As noted in the NAM's detailed submission, this policy remains an ongoing challenge for manufacturers and a negative signal about Australia's commitment to an innovative environment. The policy, which has been used multiple times since its creation in 2012, disincentivizes companies that seek to enforce or defend their legitimate, government-granted patent rights.

The policy appears to be inconsistent with Australia's key international commitments, including those under the World Trade Organization. Article 41(1) of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights provides for the practical availability of enforcement procedures that "permit effective action" against IP infringement, including "expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements."